Remarks

This is in response to the non-final Office Action mailed October 19, 2006. Claims 1-8 and 21-24 remain pending. Reconsideration and allowance are requested for the following reasons.

I. Claim Amendments

Non-elected claims 10-20 are canceled without prejudice or disclaimer as to their future prosecution. Claim 9 is canceled, and subject matter from claim 9 is incorporated into claims 1 and 21. Claims 1 and 21 are further amended, support for the amendments being found, for example, at page 24, lines 24-28 of the present application. Claim 2 is amended to address a formality. All claims are in condition for allowance.

II. Claim Objections

Claim 2 is objected to because of a formality. Claim 2 is amended to address the formality. Reconsideration and removal of the objection are therefore requested.

III. Claim Rejections - 35 U.S.C. § 102

Claims 1 and 4-7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hunn et al., U.S. Patent Application Publication No. 2004/0158207 A1. This rejection is respectfully traversed, and reconsideration is requested for at least the following reasons.

Claim 1 is directed to a method for introducing an infusion device into a subcutaneous layer of skin of a patient. Claim 1 recites, in part, allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by moving the needle of the insertion device relative to the sleeve. Claim 1 further recites, upon full insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically retracting the needle of the insertion device while leaving the infusion device positioned on the skin of the patient.

It is advantageous to allow the patient to manually insert the needle into the patient's skin so that the patient can control the timing and speed of the insertion. In addition, it is advantageous to automatically retract the needle once the cannula has been fully inserted to

protect against inadvertent contact with the needle and to limit dwell time of the needle. See p. 30, l. 27 - p. 31, l. 7 of the application.

Hunn discloses devices for inserting a cannula into tissue. A device shown in Figures 1 and 2 is an entirely manually-actuated device, in that the device requires the user to manually insert and manually retract a needle. Specifically, the device includes an operating element 7 connected to a guiding needle 8. The operating element is moved by the patient downwards to insert the needle 8 and associated cannula 3 into the tissue. Once inserted, the patient moves the operating element 7 upwards to remove the needle 8 from the tissue. Hunn, ¶ 0065.

Alternative devices shown in Figures 9-18 of Hunn provide for automatic insertion and automatic retraction of needles using one or more springs. For example, Figure 9 shows a needle carrier 27 that is moved by an inserting spring 21 to insert the needle 8 into the tissue. Upon insertion, a restoring spring 22 is used to move the needle 8 into a retracted position. Hunn, ¶ 0073.

Hunn fails to disclose or suggest a device that allows for manual insertion of the needle by the patient, followed by automatic retraction of the needle. In fact, Hunn teaches away from such a configuration, in that Hunn is critical of the devices disclosed in EP 0 290 176 ("EP '176"). Hunn, ¶ 0004. EP '176 discloses devices wherein the needle is manually inserted by the user, and then a spring is used to retract the needle. Consequently, Hunn teaches away from the device including manual insertion followed by retraction using a spring disclosed in EP '176.

Hunn therefore fails to disclose allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by moving the needle of the insertion device relative to the sleeve, and, upon full insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically retracting the needle of the insertion device while leaving the infusion device positioned on the skin of the patient, as recited by claim 1. Reconsideration and allowance of claim 1, as well as claims 4-7 that depend therefrom, are therefore requested.

IV. Claim Rejections - 35 U.S.C. § 103

A. Claims 2, 3, and 9

Claims 2, 3, and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Mogensen et al., U.S. Patent Application Publication No. 2003/0109829. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 9 is canceled. Claims 2 and 3 depend from claim 1. Mogensen does not remedy the shortcomings of Hunn noted above. For example, Mogensen fails to disclose or suggest allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by moving the needle of the insertion device relative to the sleeve, and, upon full insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically retracting the needle of the insertion device while leaving the infusion device positioned on the skin of the patient, as recited by claim 1. Reconsideration and allowance of claims 2 and 3 are therefore requested.

B. Claim 8

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Larsen et al., U.S. Patent No. 6,736,797. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 8 depends from claim 1. Larsen does not remedy the shortcomings of Hunn noted above. For example, Larsen fails to disclose or suggest allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by moving the needle of the insertion device relative to the sleeve, and, upon full insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically retracting the needle of the insertion device while leaving the infusion device positioned on the skin of the patient, as recited by claim 1. Reconsideration and allowance of claim 8 are therefore requested.

C. Claims 21-24

Claims 21-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mogensen in view of Hunn. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 21 is directed to a method for introducing an infusion device. Claim 21 recites, in part, allowing a patient to manually move a needle of the insertion device relative to the sleeve from the delivery state to a trigger state to thereby introduce a cannula of a site into the skin, and automatically retracting the needle to place the insertion device in a retracted state.

Claim 21 is therefore allowable over Mogensen and Hunn for at least the same reasons as those provided above. Reconsideration and allowance of claim 21, as well as claims 22-24 that depend therefrom, are requested.

V. Conclusion

Favorable consideration in the form of a Notice of Allowance is requested. Please contact the undersigned attorney with any questions.

Respectfully submitted,
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